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EXAMINER

PONNALURI, PADMASHRI

ART UNIT

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41

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>08/574,461</b>	Applicant(s) <b>Barone et al</b>
Examiner <b>Padmashri Ponnaluri</b>	Art Unit <b>1627</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Jan 29, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-8, 10-15, and 37-56 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-8, 10-15, and 37-56 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

1. The amendment H, filed on 1/29/02 has been fully considered and entered into the application.
2. New claims 40-52 have been added by the amendment H, filed on 1/29/02.
3. Claims 1-8, 10-15, and 37-52 are currently pending and are being examined in this application.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-8, 10-15 and 37-39, and 40-56 (newly added) are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lam et al (US Patent 5,640,489), for the reasons set forth in the previous office action mailed on 10/5/01.
6. Claims 1-8, 10-15 and 37-39, and 40-56 (newly added) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam *et al* [5,640,489; 102(e) date of at least 7/2/91] in view of Holmes [US 5,679,773] and applicants' disclosure of the prior art teachings, for the reasons set forth in the previous office action mailed on 10/5/01.
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 40-48, 50, 52-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added claims 40-48, 50, 52-56 briefly recite a method of monitoring polymer array synthesis which encompass a genus of polymers that is indefinitely large and includes libraries of: carbohydrates, polyolefins, polysulfones, polyureas, polycarbonates etc.

The instant specification description is directed to peptide (polymers) and nucleotide (polymers) libraries which do not provide adequate representation of the claimed method of preparing the genus nor representative of a substantial portion of the claimed genus.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

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Although directed to DNA compounds, this holding would be deemed to be applicable to any compound or method which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics polymers prepared by the claimed method. The specification does not describe ‘structural features common to the members of the genus, which features constitute a substantial portion of the genus.

The specification description of *peptide array* and *oligonucleotide array* is not representative of the claimed genus ‘polymers’. The specification does not sufficiently teach methods for preparing any other types of arrays, i.e., how to link them to the support using cleavable linkers or how to label these polymers. Further, the claimed genus encompasses diverse polymer libraries which are yet to be prepared or envisioned, which further evidences that the disclosed structural features of libraries (they are polymers made of monomers) do not constitute support for the claimed genus or a substantial portion of the claimed genus. Thus, peptide array or oligonucleotide array do not represent a substantial portion of the claimed genus. The specification does not attempt to describe the structural features that are common to all polymers. Therefore, the description provided by the specification does not allow a skilled artisan to visualize or recognize the identity of the members of the genus

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Additionally, the narrow scope of examples directed to specific peptides or nucleic acids are clearly not representative of the scope of array of compounds of the presently claimed invention.

9. Claims 40-48, 50, 52-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleotides, peptides and peptide nucleic acids does not reasonably provide enablement and array of diverse polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 40-48, 50, 52-56 are directed toward a method of monitoring polymer array synthesis. The disclosure teaches the synthesis and addition of a label to DNA and peptide polymer arrays, subsequent cleavage of the array and analysis of the resulting mixture of polymers wherein the individual members of the array are detected by a property of the label added. However, the preparation of arrays of diverse arrays of polymers, especially those limited of length (specific number of units) and incorporation of labels into any polymer does not appear to be within the scope of reasonable experimentation. The factors to be considered in a determination of undue experimentation are disclosed in *In re Wands*, (U.S.P.Q. 2d 1400 (CAFC 1988)). The factors to be considered include: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the predictability of the art and the breadth of the claims.

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A number of factors would prevent one of skill in the art from practicing the invention without undue experimentation, these are summarized as follows:

- 1) The specification fails to give adequate direction and guidance in the preparation of arrays of polymers commensurate in scope with “diverse polymers” as set forth in the claims. Moreover, as one must be able to control the length of the polymers in the claims to a specified number of monomers the chemistry used for preparation of many polymers (bulk homogeneous and heterogeneous catalysis) cannot be applied. Moreover, there is no teaching commensurate with the required incorporation of labels into “diverse polymers,” only the incorporation of labels into peptides, and nucleotides.
- 2) Applicants have failed to provide working examples that are commensurate in scope with the unlimited polymers claimed.
- 3) The breadth of the claims encompasses a literally any polymer such as the polyolefin, methacrylate, polycarbonates, carbohydrates, polysulfones etc.
- 4) The state of the prior art is such that methods of preparing polymers limited in the exact number of monomeric units is not widely practiced except in the nucleotide and peptide areas. Thus, one has to develop synthetic routes capable of limiting the exact number of monomeric units incorporated into any polymer (generally by step wise addition of monomers) and means of labeling the corresponding resulting polymers.
- 5) The art is inherently unpredictable because predicting a priori how to prepare any single polymer cannot be done with certainty. The situation is compounded by the necessity that the

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chemistry must be flexible enough to accommodate differing subunits and still result in the production of the expected member in each position of the array.

Therefore, while it is true that the level of skill in the art is high, it would require undue experimentation to make and use the invention commensurate in scope with that claimed in the absence of explicit guidance as to a means of preparing and labeling any polymer as set forth above.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-8, 10-15, 37-39, and 40-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-17 of U.S. Patent No. 5,843,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a testing method for nucleic acid array and instant claims are drawn to a method for testing any polymer array and the polymers include nucleic acids.

12. Claims 1-8, 10-15, 37-39, and 40-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,238,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a testing method for nucleic acid array and instant claims are drawn to a method for testing any polymer array and the polymers include nucleic acids.

***Response to Arguments***

13. Applicant's arguments filed on 1/29/02, regarding the written description rejection of claims 1-8, 10-15, 37-39 ( office action mailed on 3/22/01) have been fully considered but they

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are moot. Because the rejection has been withdrawn in view of applicants amendments to the claims (see paragraph 5, in the previous office action mailed on 10/5/01).

14. Applicant's arguments filed on 1/29/02, regarding the rejection of claims over Lam et al have been fully considered but they are not persuasive.

Applicants argue that Alm et al fail to teach or suggest synthesizing a preselected array of diverse biological polymers connected to cleavable linkers on a solid substrate. Applicants further argue that examiner is not giving due weight to Applicants recitation of the element “*preselected array*” in claim 1 and new claims 40 and 50.

Applicants arguments have been fully considered and are not persuasive, because *Lam et al teach the method can be used for synthesis of random library as well as for the synthesis of peptide library that comprise a predetermined sequence (refers to preselected array of the instant claims) (see column 10, lines 57-59)*.

Applicants argue that Lam et al only teach single bead-single polymer libraries that are random and does not teach synthesizing a spatially defined pattern of polymers on a solid support which is designed before being constructed. Applicants arguments have been considered but are not persuasive. Because Lam et al teach different embodiments polymer array libraries are known in the art including planar arrays (*i.e., spatially addressable arrays of Fodor et al*), *see for example col. 3, lines 47-52*. And Lam et al teach that the beads are partitioned in micro titer wells (see column 21), which refers to spatially addressable array. Even though preparation of

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spatially addressable libraries on supports is not preferred embodiment set forth in Lam et al, it is an immediately envisioned embodiment from the reference specification disclosure . The rejections of record have been maintained and new claims 40-56 have been added in the rejections since the new claims are same in scope of the rejected claims.

15. Applicant's arguments filed on 1/29/02, regarding the rejections of claims over Lam et al and Holmes et al, have been fully considered but they are not persuasive.

Applicants argue that lam et al fails to teach or suggest in its method steps of synthesizing a preselected array of diverse biological polymers connected to cleavable linkers on a solid substrate, whereby the diverse biological polymers occupy different regions of the substrate. Applicants argue that Lam et al counsels against the use of methods other than the single polymer single bead polymer synthesis approach. Applicants arguments have been considered but are not persuasive. Because even though Lam et al teach one bead and one species of polymer, Lam et al also teach that the method may be readily applied to permit the synthesis of a random peptide pool with  $10^5$  to  $10^7$  different peptide species. In the reference method each bead has one species, and several of such beads arranged in a multi well plate would read on spatially addressable array. Moreover, the rejection is based on different references. And applicant's arguments against the references individually (Lam et al) one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 U. S. P. Q. 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 U. S. P. Q.

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375 (Fed. Cir. 1986). The rejections of record have been maintained and new claims 40-56 have been added in the rejections since the new claims same in scope of the previously rejected claims.

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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19 April 2002

  
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